



DEPARTMENT OF HEALTH & HUMAN SERVICES

Mr. Michael H. Foley
Director, Technical Service
KMI Diagnostics, Inc.
8201 Central Avenue, NE, Suite P
Minneapolis, Minnesota 55432

MAY - 2 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k030929
Trade/Device Name: ANA Detect
Regulation Number: 21 CFR § 866.5100
Regulation Name: Antinuclear Antibody Immunological Test System
Regulatory Class: II
Product Code: LJM, LRM
Dated: March 21, 2003
Received: March 24, 2003

Dear Mr. Foley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

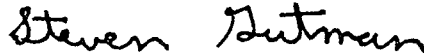
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Device Name: ANA Detect

Indications for Use

The ORGENTEC ANA Detect assay is a qualitative enzyme immunoassay (EIA) intended to screen for the presence of antinuclear antibodies (ANAs) in human serum as an aid in the diagnosis of certain systemic rheumatic diseases. This assay collectively detects, in one well, ANAs against double stranded DNA (dsDNA, nDNA), histones, SS-A/Ro, SS-A-La, Sm, SmRNP, Scl-70, Jo-1, and centromeric antigens.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use /

OR

Over-The-Counter Use

(Per 21 CFR 801.109)
(Optional Format 1/2/96)

J. B. Bouteira
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number 10030929